

**Chairman Walden  
Opening Statement  
Energy and Commerce Subcommittee on Health Hearing  
“Examining FDA’s Medical Device User Fee Program”  
March 28, 2017**

Thank you Chairman Burgess.

What a difference five years makes. The last time Congress reauthorized the Medical Device User Fee Amendments (MDUFA) in 2012, we heard story after story about venture capital drying up and innovative medical technology companies launching their products overseas, oftentimes years before American patients could benefit from them. Time after time, witnesses from all sides of the political spectrum came before this subcommittee and highlighted the burdensome, inconsistent, and opaque nature of the FDA review process as the primary driver of these alarming trends.

Thanks to Dr. Burgess and others, the Food and Drug Administration Safety and Innovation Act (FDASIA) included a number of common-sense regulatory improvements that greatly benefitted patients and spurred innovation. I also want to thank Dr. Jeff Shuren for his leadership. All of the legislation in the world could not change the deeply rooted cultural issues that were plaguing the device center at FDA. He took these criticisms to heart and then put these new legislative authorities to work.

Since 2009, the number of innovative devices approved by the FDA has almost quadrupled and American patients are benefiting from safe and effective American technologies sooner. In 2009, it took an average of 427 days before FDA even

reached a decision on a premarket approval application (PMA). As of 2015, the average review time was down to 276 days—a 35 percent decrease.

Building upon the successful implementation of the previous user fee agreement, 21<sup>st</sup> Century Cures included a number of additional bipartisan process reforms. Reauthorizing MDUFA in a timely fashion—which I remain steadfastly committed to doing—will ensure that we continue to move in the right direction. This is a good agreement that will further strengthen the agency, improve the lives of patients, and bolster America’s medical technology sector which has brought hundreds of thousands of high-paying jobs to our communities.